Medicines Control Authority of Zimbabwe

EVRF 55

EVALUATIONS AND REGISTRATION DIVISION

VARIATION APPLICATION FORM FOR ANNUAL NOTIFICATION(S)

Please note that a Separate Application should be made for each Finished Pharmaceutical Product (FPP).

Guideline: *Please complete each section of this application form electronically as a signed Word document or a text-selectable PDF document. Please ensure that the electronic and the printed versions of the completed form accompany your submission.*

SECTION 1: APPLICANT DETAILS

Company Name	
Address	
Telephone	
Email Address	
Local Representative[1] agent *i.e. name, address and contact details* (*if applicable and different from applicant*)	

[1]*Please note that the contact listed as the local representative will be the primary contact for communication for this specific application.*

SECTION 2: PRODUCT (S) INFORMATION

2.1 Associated FPP name and Registration number:

e.g. Zidovudine 100mg capsules (File number: 5504/7.13/2019)

2.2 Summary of annual notification (AN) changes *(Add rows as necessary):*

Summary of changes				
Variation number and title	**Pre-change details**	**Post-change details**	**Justification** **(Summary of studies performed to assess the effects of each change, if applicable)**	**Date of implementation**
e.g. 31a - Change in the manufacturing process of the FPP (AN)	*Instruction for passing of the slurry through 40 mesh is not included*	*At binder preparation stage, Instruction* *Included for passing of the slurry through 40 mesh.*	*To have lump free slurry*	*21 August 2018*

Note; When an annual notification involves a change in specifications or standard test procedures (STP) for an API or FPP, the signed and dated version of the revised specification and STP should be attached to the notification form, which should include a table of change history

SECTION 3.0: DOCUMENTATION CHECKLIST

The following documents have been submitted together with this application form:

Note: All documents must be provided for this application to be valid	
Supporting documentation *All parts of the dossier that are affected by a variation have been resubmitted according to the structure of the MC8 Form (Application for registration of a medicine) or CTD format as stipulated for the change(s) in the MCAZ Guideline for Submitting Applications for Variations to Registered Medicines.*	☐ Yes ☐ No
Updated MC8 form *If applicable, for each amendment which alters any information on the MC8 form and CM1 form the revised, signed and dated form has been submitted* ☐ N/A	☐ Yes ☐ No
Amendment fees *Applicable fees as per the fee schedule have been paid*	☐ Yes ☐ No
Revised, valid, dated and authorised specifications and/or standard test procedures (STP) are attached to this form. *(If applicable revised documents should include a table of change history)* ☐ N/A	☐ Yes ☐ No

SECTION 4.0: DECLARATION (*Please check all declarations that apply*).

I declare that:

☐ For each change all conditions as stipulated in the *MCAZ Guideline for Submitting Applications for Variations to Registered Medicines* for the change requested are fulfilled.

☐ As a result of the changes notified, a revised specifications or standard test procedures (STP) are attached to this form.

☐ There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

☐ The information contained herein and in supporting documents is correct and true.

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Name: _____

Signature: _____ Date: _____